

- FACT SHEET for Hospital Sterilizers -

Background

- On December 20, 2007, the Environmental Protection Agency (EPA) issued standards to reduce emissions of ethylene oxide (EO) from hospital sterilizers.
- The hospital sterilizers use ethylene oxide to sterilize medical equipment. EPA's action covers all facilities nationwide.
- The Clean Air Act defines two types of stationary sources that emit air toxics: major sources and area sources. This rule regulates hospital sterilizers as area sources.
- Area sources are smaller commercial and industrial operations that release lesser quantities of toxic pollutants into the air. Area sources emit less than 10 tons per year of a single air toxic, or less than 25 tons per year of a combination of air toxics. Sources that emit more than these amounts are characterized as "major" sources.
- This final action requires hospitals and other healthcare and dental facilities to implement a management practice to reduce ethylene oxide emissions by sterilizing full loads to the extent practicable. Facilities, which route ethylene oxide to a control device, are in compliance with the rule requirements.

RULE REQUIREMENTS

What is the Compliance Date?

- December 29, 2008 is the compliance date for an **existing source** (Constructed or reconstructed before November 6, 2006).
- New Sources (any others) must comply upon initial start-up.

Compliance Methods

There are two ways for a source to achieve compliance with this area source rule – Management practices or by use of an air pollution control device.

1. **Management practice**; requires sterilizing full loads except under medically necessary circumstances to protect human health. Hospital staff can decide the medically necessary circumstance based on generally accepted medical practices.
2. **Air Pollution Control Device**, used to reduce routed Ethylene Oxide emissions.

Testing

Testing is not required

Initial Notification - Due Date

- June 25, 2009 is the initial notification due date for an **existing source** (Constructed or reconstructed before November 6, 2006).
- 180 days after initial start-up, which is the compliance date for a **new source**.

Each facility that produces ethylene oxide emissions is required to provide an **initial** notification to Tennessee's Air Pollution Control Agency (APC). You may submit the information to APC via your own letter and certification statement or the [sample notification document](#) developed by the Small Business Assistance Program (SBEAP). Also provided below is contact information.

Keeping Records and Reporting Requirements

- Keep Records for 5 years, with 2 most recent years maintained onsite.
- Records must show date, time of each sterilization cycle, whether the cycle was run full or not, and if not what was the facilities reason for not running a full load during sterilization.
- Only an initial report is required and your report should be sent to Tennessee's Division of Air Pollution Control (APC) and the Environmental Protection Agency (EPA).

Contact Information

- You may contact the Small Business Environmental Assistance Program (SBEAP) for compliance assistance at 1- 800-734-3619 or at 615-532-8013 or by e-mail at: BGSBEAP@tn.gov or visit our website at <http://www.tn.gov/environment/small-business/index.shtml>
- Tennessee Department of Environment and Conservation
Division of Air Pollution Control (APC)
William R. Snodgrass Tennessee Tower
312 Rosa L. Parks Avenue, 15th Floor
Nashville, TN 37243
Attention: APC Hospital Sterilizer Point of Contact
- U.S. Environmental Protection Agency (EPA) or Email: CCG-NG@EPA.GOV
Sectors Policies and Programs Divisions
Attn: Mr. David Markwordt,
Hospital Sterilizers Project Leader
Research Triangle Park, NC 27711
- Interested parties can download the notice from EPA's website on the Internet under recently signed rules at the following address: www.epa.gov/ttn/oarpg/new.html. For additional information, visit the EPA's website at: www.epa.gov/ttn/atw/, or contact David Markwordt of the EPA's Office of Air Quality Planning and Standards at (919) 541-0837 or by e-mail at markwordt.david@epa.gov.